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TEMPORARY ADMINISTRATIVE ORDER
INCLUDING STATEMENT OF NEED & JUSTIFICATION

DMAP 3-2026
CHAPTER 410
OREGON HEALTH AUTHORITY
HEALTH SYSTEMS DIVISION: MEDICAL ASSISTANCE PROGRAMS

FILED
01/28/2026 9:00 AM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Adopt the new High-Cost Drug Carve-Out List effective February 1, 2026

EFFECTIVE DATE: 02/01/2026 THROUGH 07/30/2026

AGENCY APPROVED DATE: 01/23/2026

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NEED FOR THE RULE(S):

In September 2025, OHA leadership and the Governor's office agreed to implement a number of changes effective January 2026 that would reduce costs and administrative burden for coordinated care organizations (CCOs). Starting January 1, 2026, select high-cost drugs are carved out from CCO capitation. This is referred to as the High-Cost Drug Carve-Out (HCDCO). OHA reviews prior authorization (PA) requests for HCDCO products. Approved treatments will be covered by OHA directly on a fee-for-service (FFS) basis according to FFS reimbursement rules. CCOs are responsible for everything else, including care coordination, drug administration, inpatient stays, transportation, etc.

There are 47 drugs on the initial HCDCO List. They all have a high cost ($500k or more per member per year) and treat a rare condition that has few, if any, other treatment alternatives. New drugs requested for review may be added to the HCDCO List up to four times a year following the rulemaking process if they meet these criteria. This temporary rule change is needed to adopt the new version of the HCDCO List effective February 1, 2026, which adds etuvetidigene autotemcel (Waskyra), a gene therapy used to treat Wiskott-Aldrich Syndrome when a suitable stem cell transplant donor is not available.

JUSTIFICATION OF TEMPORARY FILING:

(1) Describe the specific consequences that result from the failure to immediately adopt, amend or suspend the rule(s): CCOs would be required to pay for the new drug being added to the 2/1/2026 HCDCO List. The cost of such new drugs are factored into the trend rate for the capitation payments made to CCOs, but this adjustment is spread over all CCOs, and would not offset the drug costs experienced by the individual CCO(s) that might have a member in need of this very expensive therapy. By not updating the HCDCO List, this could materially impact the finances of a CCO experiencing a request for this high-cost drug.

If a newly approved FDA drug clearly qualifies for inclusion on the HCDCO List and is not added to the list as soon as practicable, there will be confusion for the providers and administrative burden for the CCOs and OHA if it is added to the HCDCO List at a later time.

(2) Who would suffer these consequences: CCOs, OHA and providers.

(3) Why or how failure to immediately take rulemaking action would cause these consequences: Leaving the rule as currently written would keep the reference to the current 1/1/2026 HCDCO List. The new drug being added to the 2/1/26 list received FDA approval in December 2025 and could be requested at any time for pediatric patients ≥ 6 months and adults. Because it is a new therapy, there may be some pent-up demand for individuals who would benefit from this curative treatment who do not have a matched donor for a transplant. This would expose a CCO, and in particular smaller CCOs, to the possibility of having to pay millions of dollars for a member needing this therapy, without any directly corresponding amounts through their capitation payments.

Not adding the new drug to the HCDCO List through a temporary rule as soon as it comes to market and adding it through permanent rulemaking instead would create confusion with providers. They initially would need to request prior authorization from the CCO to provide the therapy for the member, but would later need to make the request to OHA for other members requiring the therapy in the future.

(4) How the temporary action will avoid or mitigate those consequences: The temporary rule will incorporate the change reflected in the February 1, 2026 HCDCO
List.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

The "High-Cost Drug Carve-Out List" available at www.orpdl.org.

AMEND: 410-141-3855

RULE SUMMARY: Incorporates, by reference, the new High-Cost Drug Carve-Out (HCDCO) List. The new drug etuvetidigene autotemcel (brand name Waskyra) is being added to the HCDCO List effective February 1, 2026.

CHANGES TO RULE:

410-141-3855
Pharmaceutical Services
(1) Prescription drugs are a covered service for conditions that are described in the funded region of the Prioritized List of Health Services, as described in OAR 410-141-3820. MCEs shall pay for covered prescription drugs except:¶
(a) As otherwise provided, mental health drugs that are in Standard Therapeutic Class 7 (ataractics-tranquilizers) or Standard Therapeutic Class 11 (psychostimulants-antidepressants) (based on the National Drug Code (NDC) as submitted by the manufacturer to First Data Bank);¶
(b) FDA-approved formulations of valproic acid and its derivatives, lamotrigine, and xanomeline/trospium and those drugs used to treat severe mental health conditions that the Authority specifically carved out from capitation according to section (11) of this rule;¶
(c) Drugs covered under Medicare Part D when the member is fully dual eligible; and¶
(d) Prescriptions for Physician Assisted Suicide under the Oregon Death with Dignity Act, for which payment is governed by OAR 410-121-0150.¶
(e) Drugs appearing on the High-Cost Drug Carve-Out (HCDCO) List dated ~~1~~2/1/2026, appearing at www.orpdl.org, and included here by reference. MCEs will be responsible for all other associated costs, including non-emergency medical transportation, care coordination, inpatient hospital services and other medically necessary expenses.¶
(A) Drugs meeting the following general criteria will be considered by the Authority for inclusion on the HCDCO List:¶
(i) Have an estimated acquisition cost of $500,000 or more per member over a 12-month period;¶
(ii) Are indicated for rare conditions; and¶
(iii) Have few alternatives, as determined by the Authority.¶
(B) To add a drug to or remove a drug from the HCDCO List:¶

(i) The MCE shall submit a request to the Authority containing all the following information:¶
(I) The drug name;¶
(II) Whether the drug is recommended to be added to or removed from the HCDCO List;¶
(III) The estimated per member acquisition cost of the drug for a 12-month period;¶
(IV) The FDA-approved indications for the drug;¶
(V) Any alternative treatments to the drug for these indications; and¶
(VI) Any additional considerations the Authority should give to adding or removing the drug.¶
(ii) If the Authority approves an MCE request for a drug to be added to or removed from the HCDCO List, the Authority shall revise the HCDCO List and amend subsection (e) of this section (1) according to the rulemaking process described in ORS 183.333-183.335 effective no later than:¶
(I) The following January 1st, for requests submitted between January 15th - July 14th;¶
(II) The following July 1st, for request submitted between July 15th - January 14th.¶
(iii) The Authority may add a drug to or remove a drug from the HCDCO List at any time using the rulemaking process described in ORS 183.333-183.335.¶
(2) MCEs may use the statewide Practitioner-Managed Prescription Drug Plan under ORS 414.330 to 414.337.¶
(3) MCEs may use a preferred drug list if it allows access to other drug products not on the drug list through prior authorization.¶
(4) As specified in 45 CFR 156.122 and 42 CFR 438.10, MCEs shall publish up-to-date, accurate, and complete preferred drug lists, including any tiering structures, that have been adopted and any coverage criteria or other restrictions on the way certain drugs may be obtained. MCEs shall ensure that:¶
(a) The preferred drug list is easily accessible to members and potential members, state and federal government, and the public;¶
(b) The preferred drug list is accessible on the MCE's public website in a machine-readable format through a clearly identifiable web link or tab without requiring a member to access account or policy number;¶
(c) Be made available in paper form if requested by a member; and¶
(d) If an MCE has more than one plan, members may be easily able to discern which preferred drug list applies to which plan.¶
(5) The preferred drug list shall:¶
(a) Include Federal Drug Administration (FDA) approved drug products for each therapeutic class sufficient to ensure the availability of covered drugs with minimal prior approval intervention by the provider of pharmaceutical services;¶
(b) Include at least one item in each therapeutic class of over-the-counter medications; and¶
(c) Be revised periodically to assure compliance with this requirement.¶
(6) MCEs shall cover at least one form of contraception within each of the 18 methods identified by the FDA. As set forth in OAR 410-141-3515, the member may refer themselves directly to family planning services without getting a referral from a PCP or other participating providers.¶
(7) Prior Authorization for prescription drug requests shall be addressed by the MCEs as described in OAR 410-141-3835.¶
(8) MCEs shall authorize the provision of a drug requested by the Primary Care Provider or referring provider if the prescriber certifies medical necessity for the drug such as:¶
(a) The equivalent of the drug listed has been ineffective in treatment; or¶
(b) The drug listed causes or is reasonably expected to cause adverse or harmful reactions to the member.¶
(9) MCEs may not authorize payment for any Drug Efficacy Study Implementation (DESI) Less Than Effective (LTE) drugs that have reached the FDA Notice of Opportunity for Hearing (NOOH) stage, as specified in OAR 410-121-0420 (DESI)(LTE) Drug List. DESI LTE drugs are identified by the Covered Outpatient Drug (COD) Status equal to 05 or 06 in the federal "Drug Products in the Medicaid Drug Rebate Program" list available at: https://data.medicaid.gov/¶
(10) The Authority shall pay for a drug that is not included in the global budget pursuant to the Pharmaceutical Services program rules (chapter 410, division 121), unless otherwise provided in this rule. An MCE may not reimburse providers for drugs carved-out in section (1) of this rule.¶
(11) Making changes to the carve-out list of mental health drugs in subsection (1)(b) of this rule:¶
(a) Adding mental health drugs to the carve-out list.¶
(A) An MCE may seek to add drugs by submitting a request to the Authority. The request must contain all the following information:¶
(i) The drug name;¶
(ii) The FDA-approved indications that identify the drug may be used to treat a severe mental health condition, along with any other FDA-approved indications; and¶
(iii) The reason the Authority should consider this drug for carve out.¶
(B) If the Authority approves an MCE request for a drug not to be paid within the global budget, the Authority

shall:¶
(i) Amend subsection (1)(b) of this rule according to the process described in ORS 183.335(5) within sixty (60) days of the request to exclude the drug from the global budget if the Authority determines that the drug has an approved FDA indication for the treatment of a severe mental health condition such as major depressive, bi-polar, or schizophrenic disorders;¶
(ii) Within 180 days of amending subsection (1)(b) of this rule as described in subsection (i), adopt this same amendment to subsection (1)(b) using the permanent rulemaking process described in ORS 183.335(1)-(4).¶
(C) The Authority may add drugs at any time using the rulemaking process described in ORS 183.333-183.335.¶
(b) Removing mental health drugs from the carve-out list.¶
(A) An MCE may seek to remove drugs by submitting a request to the Authority no later than March 1 of any contract year. The request must contain all the following information:¶
(i) The drug name;¶
(ii) The FDA approved indications for the drug; and¶
(iii) The reason the Authority should consider removing this drug from the list of carved out drugs.¶
(B) If the Authority approves an MCE request for a carved-out drug to be paid within the global budget, the Authority shall include the drug in the global budget for the following January contract cycle.¶
(C) The Authority may remove drugs in conjunction with a January contract cycle using the rulemaking process described in ORS 183.333-183.335.¶
(12) MCEs shall submit quarterly encounter data within 45 days after the end of the quarter pursuant to 42 CFR 438.3.¶
(13) MCEs are encouraged to provide payment only for outpatient and physician-administered drugs produced by manufacturers that have valid rebate agreements in place with the CMS as part of the Medicaid Drug Rebate Program. MCEs may continue to have some flexibility in maintaining preferred drug lists regardless of whether the manufacturers of those drugs participate in the Medicaid Drug Rebate Program.¶
(14) MCEs shall utilize a Pharmacy and Therapeutics (P&T) committee and a Drug Use Review (DUR) program. The committees may work in tandem or independent of the other, if all committee requirements for both committee types are met:¶
(a) A P&T committee must maintain written documentation of the rationale for all decisions regarding the drug list development and revisions. The committee shall follow the membership and meeting standards specified in 45 CFR § 156.122(3)(i) and (ii). Meetings shall be held at least quarterly;¶
(b) MCEs shall provide a detailed description of its P&T committee including its DUR functions on an annual basis. The report shall be in the form and manner required by the OHP. The data requested by the Authority shall be calculated to meet federal reporting obligations;¶
(c) The committee in its DUR capacity shall assure prescriptions are appropriate, medically appropriate, and not likely to result in adverse medical results. The committee must be designed to educate prescribers and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care. The committee shall include prospective DUR, retrospective DUR, and educational programs as each is defined and described by 42 CFR 456, subpart K and Section 1902(oo) of the Social Security Act [42 U.S.C. 1396a(oo)].¶
(15) As required by ORS 414.328, CCOs shall implement a synchronization policy for the dispensing of prescription drugs to members of the CCO. A "synchronization policy" means a procedure for aligning the refill dates of a patient's prescription drugs so that drugs that are refilled at the same frequency may be refilled concurrently.¶
(16) Enrolled providers are required to check the Prescription Drug Monitoring Program (PDMP) as defined in ORS 431A.655 before prescribing a schedule II controlled substance pursuant to 42 U.S.C 1396w-3a:¶
(a) Providers shall maintain documentation of the prescription drug history of the individual being treated; and¶
(b) In the case that an enrolled provider is not able to conduct the PDMP check, the providers shall maintain documentation of efforts, including reasons why the provider was unable to conduct the check;¶
(c) The PDMP check does not apply to clients in exempt populations:¶
(A) Individuals receiving hospice care;¶
(B) Individuals receiving palliative care;¶
(C) Individuals receiving cancer treatment;¶
(D) Individuals with sickle cell disease;¶
(E) Residents of long-term care facilities described in) 42 U.S.C. 1396d, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy in accordance with 42 U.S.C. 1396w-3a(h)(2)(B); and¶
(F) Individuals admitted to an inpatient hospital facility. This exemption shall only apply to schedule II controlled substances provided or administered to the individual admitted to the inpatient hospital facility.¶
(d) PDMP requirements are in accordance with OAR 333-023-0800 to 333-023-0830.

Statutory/Other Authority: ORS 413.042, 414.572, 414.591, 414.605
Statutes/Other Implemented: ORS 414.570-414.686